Submission to the Therapeutic Goods Administration on the Medicine Labelling and Packaging Review

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Introduction

The Complementary Healthcare Council of Australia (the CHC) is appreciative of the opportunity to provide this submission to the Therapeutic Goods Administration on the Medicine Labelling and Packaging Review Consultation paper, dated May 2012.

The CHC is the peak industry body for the Complementary Medicines (CM) Industry, representing the entire industry supply chain including; manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. The CHC is committed to a high growth and sustainable CM industry. We promote industry advancement with the objective of ensuring consumers have access to CMs of the highest quality, contributing to improved population health outcomes. We are the principal reference point for our members, government, media and consumers to communicate about issues relating to the CM industry.

The CHC supports appropriate options for regulatory reform to change the presentation of information on the labels and packages of medicines to improve the visual presentation of medicines, and more importantly, improve positive health outcomes for Australians through their access to and wise use of medicines. We support and promote the objectives of the Australian National Medicines Policy (NMP), which endeavors to bring about better health outcomes for all Australians. We believe that the major changes proposed a) prominence of active ingredient on the main panel (and on three opposing panels of a carton) and b) Medicine Information Box, if applied to complementary medicines, have the potential to cause confusion to consumers and defeats the intent of the NMP and of self managing minor health conditions.

The CHC understands that this review is being conducted with consumer safety in mind and with particular regard to pharmacy and over the counter medicines. Therefore many aspects of this review are <u>not</u> suitable or easily applied to CMs.

This review focuses on the Therapeutic Goods Order 69 (TGO 69) *General requirements for labels for medicines* and will asses whether the requirements specified in this Order continue to be relevant to the objectives of the National Medicines Policy. TGO 69 specifies the requirements for medicine labels and packaging and as such covers all medicines entered onto the Australian Register of Therapeutic Goods (ARTG). It is therefore important that any proposed legislation change is applicable to both listed and registered medicines that the legislative instrument represents.

The CHC's impression of the proposal is that it is largely based on the risk profile associated with over the counter and prescription medicines. The extra regulatory requirements for labelling and packaging is considered out of proportion to listed (AUST L) and registered (AUST R) CM products, of which the TGA has considered to be low risk based on assessment of ingredient safety and manufacturing quality. We strongly believe that the proposed changes will have a negative impact on consumers, retailers and complementary medicine business, for the reasons outlined in this submission. Given the low risk and safety profile of complementary medicines, we believe that the standardisation of ingredients as proposed on the medicine labels will be impractical and unworkable for the CM industry. The consultation paper should be re-drafted to include a specific focus on the applicability of the proposed changes to CMs.

The Complementary Medicine Industry

Complementary Medicines (CMs) and natural healthcare products are vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. CMs comprise traditional medicines, including Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines. CMs are generally available for self selection by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. The majority of CMs are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health[1].

There are over 300 complementary medicine companies in Australia generating around $2 billion in annual revenues. Australian companies export around $200 million in complementary medicines to more than 20 countries in Southeast Asia, Europe and The America's, and this continues to grow at higher rates than domestic consumption[2]. In Australia, the industry generates around 5,000 highly-skilled manufacturing jobs, and indirectly supports a further 60,000 jobs. The global market has been estimated at $US 83 billion annually[3].

Production of CMs in Australia is a substantial industry, with 59 TGA approved manufacturing facilities for listed medicines (including CMs, sunscreens and over-the-counter medicines). Over 75% of Australians use CMs, so it is not surprising that the majority of consumers can name the exact CM product they purchase and why.[4]

Australia's complementary medicines industry continues to lead the world in the development of global benchmark standards in safety, quality and efficacy.

The Regulatory Environment

The CHC is of the opinion that this consultation has not given due consideration to the principles of good regulatory policy. In that:

- all regulation imposes costs on the community;
- there needs to be consideration of the fundamental principles of a cost benefit analysis such as the Regulatory Impact Statement (RIS); and
- Council of Australian Governments principles which include:

The CHC identifies that there are a number of applicable legislative instruments that cover the labelling and packaging of goods in Australia, namely: The *Therapeutic Goods Act 1989* (the Act) which, specifies that therapeutic goods must not be imported, supplied or exported if they do not meet applicable standards; a number of Therapeutic Goods Orders (Orders) specify standards relating to the labelling and packaging of therapeutic goods as identified at attachment 1 of the consultation document; the Standard

[1] Source TGA, http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm
[2] CHC Complementary Medicines Industry Audit May 2011, available by request
[3] The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, pp13
[4] My Opinions Research for CHC May 2011

for the Uniform Scheduling of Drugs and Poisons (the Poisons Standard), as adopted by state and territory legislation in relation to poisons labelling and other Commonwealth regulatory authorities such as the Office of Chemical Safety. Other mandatory requirements include the Required Advisory Statements of Medicines Labelling (RASML). The Labelling Order makes it mandatory for medicine labels to include any label advisory statements specified in RASML. Each legislative instrument has an associated guidance or explanatory document specific to the prescription, over the counter and complementary medicine sectors. With approximately nine of these guidance documents, including the industry code of practice, it is no wonder all stakeholders are calling for a more streamlined approach to labelling and packaging of medicines.

Sponsors of listed medicines are already required to certify that the medicines meet a range of requirements. In particular, they must certify that:

- the medicine is eligible for Listing;
- the presentation is not unacceptable;
- the medicine is safe for the purposes for which it is to be used; and
- evidence is held to support any claim made in relation to the medicine.

Listed medicines may only make limited therapeutic claims. Listed medicines are not permitted to include substances that are scheduled in the Poison Standard and can be identified by the presence of an 'AUST L' number on the medicine label.

The CHC acknowledges that clear labelling of medicine packaging assists consumers to use medicines in a safe manner and is in line with the principles of the National Medicine Policy. However, the majority of complementary medicines generally have a wide range of active ingredients present in the finished product and to list all of the ingredients on the front of the medicine label would not be feasible. A number of the regulatory proposals outlined in this consultation document will not be achievable for those products such as multivitamins, as well as those with active ingredients which are of herbal origin where genus and species names are lengthy. The CHC considers that more time is need in consultation with industry to derive workable and alternative solutions to the labelling and packaging issues.

Specific comments on Medicine Labelling and Packaging

Country of Origin Labelling

The country of origin is included in 2 locations in the example medicine labels, Figure 2 number 11 and Figure 3. The consultation paper does not go into further detail regarding the inclusion of country of origin labelling despite this not being mentioned in the current TGO 69. Clarification is required as to whether inclusion of COL is mandatory.

Warning label on main panel

It appears that the warning label on the front facing is only required in specific circumstances (i.e. where the medicine contains ibuprofen or paracetamol), however the CHC suggests the inclusion of a statement in point 4 to denote that the warning is not required in all cases for example "where required".

The proposed regulatory changes for the prominence of the active ingredients on medicine labels

1.1 – The active ingredient(s) must be listed immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name.

The CHC does not support this proposal as it would be unworkable for CM products to include all active ingredients on the label under the brand name.. The current TGO 69 requirement should be retained which state for particulars to be included on the main label except:

3(3) b - where there are two or more active ingredients that are vitamins or minerals or that are required to be quantified as the equivalent fresh or dry weight or volume under sub clauses 4(11)(b) or 4(11)(c) – it shall be sufficient compliance with this sub clause if the names and quantities or portions of these active ingredients together with the names and quantities of every active ingredient in the goods are included on the side panel or side label or on a rear panel or rear label.

1.2 On the front/main panel of the label, the active ingredient must have equal prominence with the brand name.

The CHC does not support this proposal. We believe the current requirements outlined in TGO 69 in regards to listing active ingredients on the main panel are sufficient in communicating the information to consumers. We don't see any added consumer benefit by enforcing the above proposal for CM products.

The CHC considers that with the range and complexity of CM ingredients it is more useful to have the key benefit claim prominent on the product label so the consumer can identify if that particular product will assist them. This is especially important considering the complementary medicines industry is in consultation with the TGA on the appropriate evidence required to support indications for listed medicines.

1.2.4 – the active ingredient should begin with an uppercase letter but the reminder should be in lower case.

The CHC suggests that this would require consideration of the Australian Approved Names (AAN) convention. For example, the TGA AAN is dl-alpha Tocopherol, not Dl-alpha tocopherol.

1.3 – Where there are more than 3 active ingredients, the most abundant ingredients must appear on the main label immediately below the brand name and the names, together with the quantities of every active ingredient, are to be included on a side panel/label or on a rear panel/label for the product.

The CHC has particular concern with this recommendation. The primary ingredients contributing to the effectiveness of the CM formula may not always be the most abundant ingredients by quantity. For example, selenium could be the key ingredient in a men's formula, while folic acid could be the key

ingredient in a multivitamin for pregnant women, and a herbal extract could be at therapeutic does without being one of the most abundant ingredients in the formula due to its concentration ratio and input quantity. Additionally, selenium is included in products in mcg amounts, whilst vitamin C is often in mg amounts. However, selenium's maximum daily dose is 150mcg and has more potential for toxicity at lower levels than Vitamin C. It should be noted that most proprietary combination homeopathic medicines contain an average of 10 active ingredients. Some of them contain considerably more. It would be impossible to distinguish homeopathic ingredients with similar homeopathic dilutions; there would be no "most abundant" ingredients in the case of a medicine containing, for example, ten ingredients, all of the same homeopathic dilution, in equal parts.

The CHC considers the complexity and diversity of CM ingredients has not been considered, and therefore this proposal is unworkable across all therapeutic goods and could lead to consumers being misled about the benefits of the product.

The CHC believes this proposal will cause more confusion and be misleading for consumers giving the impression that the product contains solely those active ingredients mentioned on the front portion of the label. It could be argued that this recommendation may compromise a company's legal position in relation to the *Consumer and Competition Act 2010*, as this might be considered as "misleading and deceptive". In addition there will be a repetition in active ingredients on the label, when considered across the context of the product, which would also be misleading. In particular, section 18 of the Australian Consumer Law states:

'A person must not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive'. This prohibition is not limited to the supply of goods or services and creates a broad, economy-wide norm of conduct.

By definition multivitamins contain a large number of active ingredients; to highlight just three in the manner proposed has the potential to mislead the consumer and thus, potentially breach consumer law.

In relation to CMs, this recommendation seems to pose a greater risk to consumer safety than the current recommendations that state:

3(3)(a): *where there are four or more active ingredients in the goods - in which case it shall be sufficient compliance with this subclause if the names together with the quantities or proportions of every active ingredient are included on a side panel or side label or on a rear panel or rear label of the container and primary pack for the goods;*

The current recommendation means that the consumer is driven to look at the full list of ingredients. The CHC believes that this proposal will be misleading to consumers, and poses the potential for them to believe that the three ingredients on the main label are the only ingredients in the product.

Centered on consumer safety, and to avoid multiple doses of the same active, the disclosure of only 'the most abundant' ingredients on the main label would not provide added insurance. For example, multivitamin containing zinc, a 6x ingredient cold and flu product containing zinc, and a 4x ingredient Vitamin C product containing zinc, may all have zinc listed on a part of the label other than the main label. This is a very likely scenario for CM products, as the majority contain multiple actives.

It is important to note the disconnect in the proposal across the therapeutic goods sector. Most, but not all, complementary medicines included on the ARTG are listed medicines[5], which have been evaluated by the TGA and found to be of low risk, containing only those active ingredients permitted under Schedule 4 of the Regulations. In the case of generic ingredients in one-to-two ingredient based CM products, due to the limited proprietary name use in CMs, the product name itself usually reflects the product, making it unlikely for consumers to double up on active ingredients (for example, Ginkgo 3000, Fish Oil 1000). As such, there is a lower risk profile for CM products containing the same ingredient and this should be reflected in the consultation paper.

1.4 – For products containing day and night preparations that have different formulations, the composition of each tablet must be provided immediately below the brand name and the font size must be less than 2mm in height on the main/font panel.

The CHC does not support this proposal. There are CM products that are designed to include day and night formulations. For example, a day and night menopausal formulation can contain ten actives in each formula. It would be impractical to include all 20 active ingredients directly underneath the brand name in a font size described above. With the introduction of the Medicine Information Box or similar, we do not see any additional benefits to list all active ingredients on the main panel for low risk CM products.

1.5 – The active ingredient must be included with, and of equal prominence as, the brand name on at least 3 non-opposing faces of a carton.

The CHC does not support this proposal. We believe that the Medicine Information Box or similar is sufficient in communicating information regarding CM product formulation in a direct and concise manner. There should be sufficient space left on the main panel to highlight claims and benefits of the product to the consumer.

The example given on Figure 3, page 17 outlines this proposal in the context of registered medicines (AUST R) only, and the options outlined under proposed regulatory changes are non inclusive of complementary medicines. For multi ingredient CM products, such as herbal formulas containing over 4 ingredients, there would be limited space to list the active ingredients with, and in equal prominence, to the brand name on 3 non-opposing sides of a carton.

The CHC strongly encourages the TGA to further consult with all stakeholders and conduct consumer use testing on sample products covering the prescription, OTC and complementary medicine range to gather its own evidence base to support appropriate regulatory change for the labelling and packaging of medicines.

The CHC considers a font size of no less than 1.5mm in height to be the smallest legible. The CHC suggests that a clear graphic representation be provided for industry. For example, the labelling guideline published for the Veterinary Medicines in Australia specifies that:

- Letters with ascenders or descenders, such as b, f, g, h, y, t etc are to be a minimum of 1.5mm. In printing terms the upper case of 1.5mm equals 6 points.

[5] http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm

- Letters without ascenders or descenders, such as a, e, i, o, u, m, r etc are to be a minimum of 1mm. Use of 6 point type provides lower case “o” or “n”, for example with a height of 1mm.

Warning and Uses on the main label

The CHC notes that there are warning statements and an indication box shown on the main panel in the examples provided on Figure 2, 3, and 4. The CHC does not support the approach as outlined as it will result in overcrowding of the main panel with information that can be easily located in the Medicine Information Box or similar.

The proposed regulatory changes for look-alike sound-alike names and look-alike packaging

3.1 – Sponsors of new medicine would be required to submit evidence of risk assessment of the proposed labelling and packaging. The TGA will work with industry to develop guidance for this assessment, which may include consumer testing or risk assessment checklists similar to those used in other countries. The TGA is investigating methods to electronically screen proposed brand names against already existing brand names to identify potential LASA names.

For complementary medicines, the CHC does not support the proposals outlined for LASA names. While we do appreciate the objective of avoiding possible harm that may result from confusing different medicines because of similarities in the names or packaging of medicines, within the CM industry there is very little in the way of ‘use of the same brand name for a range of products with different active ingredients resulting in look-alike medicine branding’. Not withstanding, the proposal is overly cautious for CMs and will result in reduced speed to market and minimised product opportunities for industry.

With regard to sound-alike brand names, it is evident from the table on page 21 that this is of concern for pharmacy medicines. The CHC can not at this time offer any examples of similar LASA complementary medicine names. Proprietary names are not common in the CM industry. Unlike pharmacy medicines, CMs can not trade off proprietary names such as Aldomet, as these names are too abstract for consumers. The CHC suggests that the proposals for regulatory change in this area be written to combat sound-alike medicines for pharmacy medicine only.

Risk assessment of labelling and packaging should not be required for listed CMs as they are relatively low risk products. If a standard format for a medicines information box is required, this should be more than sufficient to ensure that consumers are well informed for self selection.

Within the CM industry, there are many ‘brand/product names’ that are identical, such as Fish oil 1000. A recent ARTG search of ‘fish oil 1000’ returns 38 products with this in the product name. For certain CM products, Sponsors rely on the product name to state what the product is for eg. Headache Relief, or the product name states the ingredient in the product eg St John’s Wort. This obviously results in product names being quite similar.

Submitting evidence of risk assessment for the proposed labelling and packaging will slow down the listing process for AUST L products, a process upholding the objectives of the Australian National Medicine Policy - of timely access to medicines. In addition, does the TGA propose to assess the risk assessment? If so, how will this be resourced and cost recovered?

3.2 & 3.3 - In relation to applications to include a new medicine or to change the labelling and packaging of existing medicines in the Australian Register of Therapeutic Goods (ARTG), if the medicine brand name differs from another product included in the ARTG by three letters or fewer, the presentation of the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product or other medicine. During the implementation of this change, the TGA will work with the medicines industry to develop guidelines to provide clarity about these proposed requirements.

The CHC does not support this proposal. This proposal would create ambiguous areas, even with the implementation of guidelines

Additionally, the CHC suggests this proposal could create a legal minefield in regard to the subjective statement '*the proposed medicine label and packaging must use colours and designs that contrast with the medicine label and packaging of the existing product'.*

Also, there will be more than one existing product on the market with brand names that differ by 3 or fewer letters. As mentioned, a recent ARTG search of 'fish oil 1000' returns 38 products with this term in the product name. This proposal would also make it near impossible to present a uniform brand/company appearance, which could confuse the consumer even further. The proposal would require a pre-assessment process creating obstacles for efficient market entry of listed medicines and the current IT system would not have the ability to distinguish between different product doses eg Fish oil 1000mg vs 1500mg or different product names (folic acid or folinic acid) in the Product Name filed.

3.4 – Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine.

The CHC does not support this proposal. Generally, consumers are motivated by their individual health concerns and may be unaware of the particular product/ingredient that may be well known for one use is also beneficial for another. Sponsors can simplify this by highlighting the benefits as packaging through sub branding and as the claim or benefit is required to be substantiated at the time of listing, this communication pathway should be retained.

The above proposal would cause issue in the scenario where a grandfathered CM product may later become listable. If this scenario occurred, the Sponsor may wish to keep the product name as it was sold as a registered medicine as theoretically there is no difference between the two products. As the brand names and packaging for AUST L products are not pre approved by the TGA prior to entry on the ARTG, how would such a recommendation be implemented?

The CHC suggest that restricting Sponsors in the way their medicine is to be presented by contrasting colours and designs, would not contribute to consumers or healthcare professionals making safer decisions. The CHC reiterates the vital importance of education in industry, in particular consumer

education on how to read medicine labels suitably. Placing this information in one area of the packaging will assist consumers when making decisions on selecting complementary medicines, compared to altering the colours and designs of the packaging. The proposed regulatory options are restrictive and imposing on industry, especially for those products and brands well known for their image and product name. Hence, they will be disadvantaged when a requirement such as changing colours and designs is imposed. Industry invests heavily in creating a brand image and this does not only involve the name of the brand but also the overall presentation. The CHC believes s that altering colours and designs of the brand name does not offer a solution in assisting consumers to make safer decision when selecting complementary medicines.

No consideration has been given to registerable CMs in that certain registerable CMs, such as a pregnancy multi, include other products under the same brand that are listed medicines. Such a proposal would mean the registered CM would have to be separate from the brand. There is no evidence that this approach causes harm. In addition, Medicine Kits are AUST L but can contain AUST R products, for example a men's and women's 'pre conception formula' can contain a listed men's product and registered women's product (due to the iron and folate content). Clarification is required as to whether kits that include AUST R products will be impacted by being listed under the same brand name and moreover what benefit to consumer health and safety is derived by the implementation of such a recommendation.

The proposed regulatory changes for Standardised Information Format: the Medicine Information Box (MIB)

Issue: inconsistent placement and presentation of key medicine information on the labels of medicines

In principle, the CHC agrees with a standardised information format. The standardisation of information on medicine labels will help consumers to make decisions about medicines.

We recommend, in the interest of consumer health and safety, the TGA considers an automatic exemption for listed medicines to allow mention of prescription medicines and forms of serious disease, but only to permit a warning statement – for example, if concurrent use is contraindicated: *CM product X should not be taken at the same time as prescription product Y, which is used to treat/prevent* said *disease.* This automatic exemption would only be applicable to words contained within the information box or similar. Currently, section (5)(2) of the Therapeutic Goods Advertising Code (TGAC) prohibits the inclusion of such information, unless prior approval is given under the *Therapeutic Goods Act 1989*. The inclusion of such warning statements would assist consumers in making safe medicine choices.

We also strongly believe in Australia's National Medicine Policy that states everyone has a part to play in the Quality Use of Medicines (QUM). Currently, a MIB is not mandatory for labels and packaging and it may not always be feasible, depending on the size of the label *and* the size of CM product formulas. The amount of proposed mandatory information (active ingredient, indications, warnings, allergen, contraindication and storage) would not always fit onto a single panel of a label or carton and still meet the minimum font size requirement.

The CHC notes that the supporting evidence used to make this regulatory proposal for a MIB is based on a study on prescription drug labels[1] and in the form presented is an excessive regulatory barrier for low risk CMs.

Our members have identified that there are also technical considerations to the proposal mentioned here, around where the batch coding (machine and packaging dependent) and the barcode (depending on the specific requirements related to sales channels involved) could be positioned on the label and cartons.

4.1 – mandatory information on labels and packaging of non-prescription medicines and complementary medicines is presented in a standardized Medicine Information Box, based on the US FDA Drug Facts Box …

The CHC has concerns with regard to the technicality of the above proposal. In regard to global harmonisation, the use of the term 'Medicine Information Box' would have implications for products also sold in New Zealand, where they are regulated as Dietary Supplements. It would be confusing and inconsistent to have a MIB on a dietary supplement.

In regard to allergen information, Sponsors should have the ability to include extra allergen information (such as contains no added gluten) on a pack. The examples provided in Figures 6 & 8 include a statement related to the physical appearance of the product under the heading 'Storage information'. Such descriptors may be useful for consumers to make a decision on whether the product is still suitable for consumption, but it should be noted that the descriptor specifically related to colour is very subjective and it is common for there to be batch to batch variation in colour when it comes to natural origin materials such as herbal extracts and oils. The consultation paper does not go into further detail regarding the inclusion of tablet appearance despite that this is not currently required under TGO 69. Further clarification is recommended regarding whether the inclusion of tablet appearance is mandatory.

4.2 – the font height for information must be no smaller than 1.5mm, with heading height at least 2mm.

The CHC supports the current mandatory requirements for font size of no smaller than 1.5mm in height. However, for some CM products, the mandatory information prescribed for the MIB cannot physically fit onto one panel of a carton or a label. The CHC acknowledges that label space versus minimum print height is often an issue in industry. However, the CHC strongly resists the proposed regulatory option for mandatory pack inserts as this would substantially increase the cost of CMs. The TGA should permit other label solutions (such as peel back concertina labels) without requiring special approvals for alternative solutions to meeting the print height requirements.

4.3 – The Medicine Information Box must have a white background with black text. Heading must be highlighted or bolded so they are sufficiently emphasised.

The CHC questions how this would be expressed where there are products with black labels on the market. The CHC considers in this example the highlighted heading (reversed white texts) proposed for the MIB would reduce readability, in particular on small labels.

[1] Shank, W et al, Effect of Content and Format of Prescription Drug Labels on Medicine use: Ann Pharmacother 2007; 41:783-801.

4.4 - Where there is insufficient room on a single face of a package, the box may be split over more than one face. In these instances a pack insert may also be included containing the medicine information box as a continuous table.

The CHC does not support this proposal as it is currently written. The TGA could consider a prescribed sequence of how mandatory information must appear on the label, but without a prescribed format such as a Box. This would provide Sponsors with flexibility to present mandatory information in a clear and concise manner without the constraint of a MIB or pack inserts. Such an option should be considered as it will reduce the financial impacts related to pack inserts for Sponsors of CMs.

4.6 – for products containing more than three active ingredients, or products in small containers, there may be insufficient space on the medicine container or primary packaging for a complete Medicine Information Box. In these cases a complete MIB should be included as a pack insert. The minimum information to be included on the label will include Directions, and Warnings and Allergy Information.

The CHC does not support this proposal. A pack insert may be an option for small containers, but the cost involved could be an inhibiting factor for industry. The CHC considers that directions, warnings and allergen information to be important but not sufficient on their own to allow consumers to make sound purchasing decisions without access to other important information, particularly when the products are for self selection by consumers. The CHC supports options for mandatory uniform information in a set order without the restrictions of a MIB.

Blister Strip Labelling

6.1 – the brand name of the medicine, the active ingredient and the amount of active ingredient, batch number and expiry date must be repeated at least once every two units.

The CHC does not support the proposal to include the batch and expiry data more frequently on the blister strip than what is currently required. The TGO 69 currently requires the above information to appear once on each blister strip, when each dosage unit cannot be readily detached.

Batch numbering is usually applied to blister strips as a stamp at the time of manufacturer at one end of the blister strip so that packaging artwork does not have to be amended for every batch. It is not practical to implement printing of the batch number on the foil of the blister packaging.

Our members have stated that the proposed requirements would pose technical considerations, in particular the repetition of the expiry date, where the embossing of this information once every two units would not be practical once it is sealed with tablets/capsules. Such recommendations would mean that production would be slowed significantly to facilitate the online printing, resulting in significant capital expenditure and increased operating expenditure, costs that are ultimately passed onto the consumer. The CHC highlights that printing more information on the foils encourages consumers to remove the blister

from the cartons where all of the dosage instructions and warnings are located and is not in the interest of public health and safety.

6.4 – Where there are more than 3 ingredients, for example multi-vitamins packaged this way, it may be sufficient to include a single list of active ingredients printed on the foil of each blister strip. Alternatively, the brand name, together with batch number and expiry date, should be repeated on the foil.

The CHC believes the same mandatory information should be used across all products in blister strips, after the technical limitations mentioned above have been considered. The CHC supports the inclusion of brand name, active ingredients and its quantities to be repeated on the blister strip as many times as practical for formulas containing not more than three active ingredients, and at least once for formulas containing more than three ingredients. For the reasons outlined above, the CHC recommends that batch number and expiry date should be included once on each blister strip.

Small Containers

The requirement for small container labels on page 36-37 appears to state both that the container label must include the names of all actives and also that only the three most abundant must appear on the label and all of them on a primary pack and an insert. Hence, there would then be a disagreement between label and primary pack and presumably more words required to explain that the full list of ingredients is to be found elsewhere. This may be difficult if carton and insert have been thrown away, for example.

If the container is so small that it is an oral liquid ampoule or a 2.2 mL or 1 mL size, then the small container requirements for the container could not be complied with as proposed. However, further clarification is required if the current exemptions from the Labelling Order are retained in the proposal for similar applications.

Pack inserts

8.1 – Advertising material will not be permitted to be included as a separate pack insert or incorporated into an approved pack insert

It is unclear how this proposal will improve the safe and effective use of medicines. Pack inserts offer Sponsors of CMs an opportunity to provide consumers with information about other products they may benefit from. It is reasonable to prohibit the advertisement of prescription medicines on pack inserts, however, such restrictions should not apply to listed medicines, as long as the advertising material complies with the Therapeutic Goods Advertising Code (TGAC), and as such this regulatory proposal should exclude CMs. Pack inserts should only be required if all the necessary information cannot be included on the product label.

The CHC notes that no definition for 'advertising material' is provided for throughout the consultation document. It would be helpful for industry if the definition were to be included in the document under the glossary.

8.2- a pack insert must be in a form separate to the packaging; i.e. it cannot be printed on the inside of the carton.

The CHC supports the above proposal.

9- it is proposed that this expert advisory body will provide advice to the TGA on product –specific as well as general matters relating to medicine labels and packaging.

The CHC supports the idea of having a labels and packaging advisory committee, if the details of the terms of reference for that committee are addressed and agreed to in consultation with industry. The objective of such a committee should include provisions for the development of clear guidelines and opportunities to expedite evidenced-based decision making in relation to the labelling and packaging of medicines.

Additional comments

Transition period

It is proposed that a three year transitional period for existing products will be permitted after the proposal is a registered legislative instrument in mid 2013. The CHC highlights the extent of regulatory reform for complementary medicines and in particular to consider aligning transition timeframes with other large reform projects such as the coded indications project and evidence required to support listed indications. Such consideration would allow for a more efficient transition for industry with regard to these costly and substantial changes.

Overall packaging design

Overall the packaging design proposed is likely to result in reduced competiveness in the market place for CM products. Every product will look almost identical except for the color and design used on the main panel with all the other information in black and white. The proposal could have a significant impact on overseas customers who take common packaging sold in Australia, resulting in trade barriers because it is usually too expensive to have market-specific packaging for 'less' regulated countries and or smaller volume/value markets.

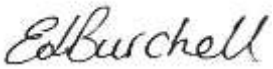
Conclusion

The CHC thanks you again for the opportunity to make this submission. In general, the CHC is supportive of appropriate regulatory reform that will echo the objectives of the Australian National Medicines Policy.

While the CHC, in general, acknowledges the proposed benefits of the alternate regulatory approach outlined to the broader over the counter and prescription medicines sectors, we look forward to a TGA proposal that will provide more specific details on compliance requirements for listed complementary medicines.

In finishing, the complementary medicine sector is different to the prescription sector in ways that are not always recognised. The broader effects of regulation should always be considered, and the often undervalued effects of regulation – on improving public health and on industrial policy – should receive more attention. The CHC are keen to continue working with the TGA to address the recommendations of the Government's Blueprint Report in a positive and constructive way as a part of the reform of the complementary medicines regulatory framework.

Yours sincerely,



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